REMARKS

This paper is in response to non-final Office Action dated 12/06/2002. Payment for response time extension, new power-of-attorney, rule 132 affidavit, information disclosure form, and materials for sequence rules compliance are submitted herewith. Please note that attorney-docket-number for this application has changed. Additionally as appropriate to help clarify any questions the Examiner may have in this case, Applicants shall contact the Examiner to propose a telephone conference preferably during early May 2003.

Claims 1-24 are rejected by the Examiner under 35 USC 112, first paragraph, for failing to enable the claimed invention, also for containing subject matter not described in the specification in such way to reasonably convey to one skilled in relevant art that the inventors, at the time the application was filed, had possession of claimed invention. Applicants respectfully disagree with the Examiner's rejection; accordingly in compliance with the enablement requirement, Applicants hereby submit an affidavit under 37 CFR 1.132 to overcome the rejection.

Additionally, applicants kindly refer the Examiner federal court decisions in support of successful animal results as sufficient patent evidence. Archer v. Papa, 46 CCPA 835, 265 F2d 954 (1959) stated that successful use of compound on laboratory animals may be sufficient proof of utility to establish actual reduction to practice of the compound. In re Krimmel, 48 CCPA 1116, 292 F2d 948 (1961) stated that pharmaceutical applications include treatment of animals and did not indicate that the compound was necessarily intended for human use, and experimental testing demonstrated usefulness of compound, i.e., pharmaceutical application fulfills utility even when not working same for humans. Engelhardt v. Judd, 54 CCPA 865, 369 F2d 408 (1966) stated that reference to dosing humans in patent specifications does not prevent inventor from

proving actual reduction to practice of drug by successful utility testing on standard experimental animals. Rey-Bellet v. Engelhardt, 181 USPQ 453, 493 F2d 1380 (1974) stated that despite only testing compound on animals before applying for patent, conception of utility for the compound completed because testing was exercise of routine skill. Scott-Burton v. Finney, 32 USPQ 2d 1115, 34 F3d 1058 (1994) stated that Board of Patent Appeals was in error by requirement to show human testing of invention to demonstrate reduction to practice. SmithKline v. Apotex, 2001 US Dist. LEXIS 19766 (2001) stated that "humans and rats are not wholly dissimilar, but it is well within the realm of common sense that tests showing decreased uptake of a particular substance in rat brains indicates only a possibility of like chemical behavior in the human cerebrum."

Claim 24 is amended to correct antecedent basis, per the Examiner rejection under 35 USC 112, second paragraph.

The Examiner rejected claims 1-3, 7, 10-12, 15, 16, 20, 21, 22 and 24 under 35 USC 102(b) as being anticipated by Stickl (USPAT 2057627), as evidenced by Taverne et al. Applicants amend claims 1, 11, 20 and 24 to specify among other things that ... *the vaccine/solution/composition comprises a genetic vaccine utilizing a recombinant vector or modified polypeptides, the vaccine further comprising antigens that do not cause a destructive form of acne.* None of the references cited by the Examiner describe or suggest this invention.

Applicants respectfully submit that all rejections are now overcome, and thus request allowance thereof. Attached is a marked-up version of changes made to Specification and Claims, captioned **"Version with markings to show changes made."**

Respectfully submitted,

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"VERSION WITH MARKINGS TO SHOW CHANGES MADE"

Please amend claims 1, 11, 20 and 24; claims 2-10, 12-19 and 21-23 are un-amended:

In the Claims:

1. **(AMENDED)** A vaccine useful in preventing and treating diseases caused by a pathogen capable of infecting, or avoiding destruction by, macrophages, said vaccine comprising at least one vector that comprises at least one nucleotide sequence encoding at least one antigen derived from said pathogen, and wherein said antigen is capable of generating an immune response in a recipient thereof; wherein the vaccine comprises a genetic vaccine utilizing a recombinant vector or modified polypeptides, the vaccine further comprising antigens that do not cause a destructive form of acne.
2. **(UN-AMENDED)** The vaccine of claim 1, wherein said pathogen is *P. acnes, L. monocytogenes, S. typhimurium, N. gonorrhoea, M. avium, M. tuberculosis, M. leprae, B. abortus, C. albicans; L. major,* or combinations thereof.
3. **(UN-AMENDED)** The vaccine of claim 2, wherein said pathogen is *P. acnes.*
4. **(UN-AMENDED)** The vaccine of claim 1, wherein said vector comprises naked DNA, a recombinant viral vector, or a combination of both.
5. **(UN-AMENDED)** The vaccine of claim 4, wherein said recombinant viral vector is selected from the group consisting of adenovirus, adeno-associated virus, herpes virus, vaccinia and RNA viruses.
6. **(UN-AMENDED)** The vaccine of claim 5, wherein said recombinant viral vector is an adenovirus.
7. **(UN-AMENDED)** The vaccine of claim 1, wherein said vector further comprises a nucleotide sequence encoding an adjuvant.
8. **(UN-AMENDED)** The vaccine of claim 7, wherein said adjuvant is a cytokine.

9. **(UN-AMENDED)** The vaccine of claim 8, wherein said cytokine is IL-2, IL-12, or both.

10. **(UN-AMENDED)** The vaccine of claim 1, wherein said antigen is a lipase gene or fragments thereof, a hyaluronidase gene or fragments thereof, a phosphatase gene or fragments thereof, or combinations of the foregoing.

11. **(AMENDED)** A method of treating or preventing a disease caused by a pathogen capable of infecting, or avoiding destruction by, macrophages, said method comprising obtaining a vaccine comprising at least one vector that comprises at least one nucleotide sequence encoding at least one antigen derived from said pathogen; and administering said vaccine to a recipient in need thereof; wherein the vaccine comprises a genetic vaccine utilizing a recombinant vector or modified polypeptides, the vaccine further comprising antigens that do not cause a destructive form of acne.

12. **(UN-AMENDED)** The method of claim 11, wherein said administering comprises routes of administration comprising oral, intravenous, intramuscular, transcutaneous, subcutaneous, aerosol, ocular, rectal, intraperitoneal, intrathecal, or combinations thereof.

13. **(UN-AMENDED)** The method of claim 12, wherein administering comprises transcutaneous administration.

14. **(UN-AMENDED)** The method of claim 13, wherein said transcutaneous administration comprises applying said at least one vector to a patch, and adhering said patch to skin of said recipient.

15. **(UN-AMENDED)** The method of claim 11, wherein said pathogen is *P. acnes, L. monocytogenes, S. typhimurium, N. gonorrhoea, M. avium, M. tuberculosis, M. leprae, B. abortus, C. albicans; L. major*, or combinations thereof.

16. **(UN-AMENDED)** The method of claim 15, wherein said pathogen is *P. acnes.*

17. **(UN-AMENDED)** The method of claim 11, wherein said at least one vector comprises naked DNA, a recombinant viral vector, or a combination of both.

18. (UN-AMENDED) The method of claim 17, wherein said recombinant viral vector is an adenovirus.

19. (UN-AMENDED) A kit comprising a container and one or more patches, wherein said patches have disposed thereon at least one vector comprising a nucleotide sequence encoding an antigen derived from a pathogen, said pathogen being capable of infecting, or avoiding destruction by, macrophages.

20. (AMENDED) An article of manufacture comprising a vaccine solution disposed within a tube, vial, bottle, can, or syringe, wherein said vaccine solution comprises a viral vector comprising a nucleotide sequence encoding an antigen derived from a pathogen, said pathogen being capable of infecting, or avoiding destruction by, macrophages; wherein the vaccine solution comprises a genetic vaccine utilizing a recombinant vector or modified polypeptides, the vaccine further comprising antigens that do not cause a destructive form of acne.

21. (UN-AMENDED) The vaccine of claim 1, wherein said vaccine is in the form of an aqueous solution.

22. (UN-AMENDED) The vaccine of claim 1, wherein said vaccine further comprises a nucleotide sequence encoding a co-stimulatory molecule.

23. (UN-AMENDED) The vaccine of claim 22, wherein said co-stimulatory molecule comprises a B7 protein, a CD40 protein or both.

24. (AMENDED) A method of cosmetically improving the appearance of a person's skin who is suffering from acnes vulgaris, said method comprising the steps of obtaining a composition comprising a mixture of at least one vector that comprises at least one nucleotide sequence encoding at least one antigen derived from [said] P. acnes, and a cosmetic agent; and administering said composition to said person; wherein the composition comprises a genetic vaccine utilizing a recombinant vector or modified

polypeptides, the vaccine further comprising antigens that do not cause a destructive form of acne.